HOUSE BILL No. 1879

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-7-2-190.6; IC 12-15-35.

Synopsis: Medicaid drug formularies. Defines "therapeutic classification". Provides that a drug formulary adopted by the Medicaid program or a Medicaid managed care organization must provide for at least two alternative drugs within each therapeutic classification on the formulary. Provides that the Medicaid program or a Medicaid managed care organization may require prior authorization of a drug only to restrict access to single source drugs that are subject to clinical abuse or misuse. Provides criteria for the drug utilization review board to consider in determining whether to approve a Medicaid managed care organization's proposal to remove or restrict a single source drug. Provides that a Medicaid managed care organization may remove or restrict a single source drug only under certain conditions. (The introduced version of this bill was prepared by the interim study committee on Medicaid oversight.)

Effective: July 1, 2001.

Crosby, Crawford, Budak, Dillon

January 17, 2001, read first time and referred to Committee on Insurance, Corporations and Small Business.

Introduced

First Regular Session 112th General Assembly (2001)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2000 General Assembly.

HOUSE BILL No. 1879

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-7-2-190.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 190.6. "Therapeutic classification", for purposes of IC 12-15-35, has the meaning set forth in IC 12-15-35-17.5.**

SECTION 2. IC 12-15-35-17.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 17.5. As used in this chapter, "therapeutic classification" means a grouping of pharmacologic agents primarily characterized by a significant similarity of biochemical or physiological mechanism by which the agents as a group result in the intended positive clinical outcome.**

SECTION 3. IC 12-15-35-35, AS AMENDED BY P.L.231-1999, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food

and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs;

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within

twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(c) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

(e) The Medicaid program may require prior authorization of a drug only to restrict access to single source drugs that are subject to clinical abuse or misuse.

SECTION 4. IC 12-15-35-46, AS ADDED BY P.L.231-1999, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.

(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.

(c) The office shall forward the formulary to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:

(1) A statement of the date, time, and place at which the board meeting will be convened.

(2) A general description of the subject matter of the board meeting.

(3) An explanation of how a copy of the formulary to be discussed may be obtained.

The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

(e) In reviewing the formulary, the board shall do the following:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Make a determination that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification**,** if available, on the formulary;

(B) a process is in place through which a Medicaid member has access to medically necessary drugs; and

(C) the managed care organization otherwise meets the requirements of IC 27-13-38, **as determined by the board.**

(3) If the managed care organization requires prior authorization of a drug under subsection (l), make a determination that the prior authorization process used by the managed care organization meets the requirements of subsection (l).

(f) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendation to the office.

(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.

(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.

(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision.

(k) Notwithstanding the other provisions of this section, the office

may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.

(l) A Medicaid managed care organization may require prior authorization of a drug only to restrict access to single source drugs (as defined in section 35 of this chapter) that are subject to clinical abuse or misuse.

SECTION 5. IC 12-15-35-47, AS ADDED BY P.L.231-1999, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 47. (a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for Medicaid recipients:

(1) Removing one (1) or more drugs from the formulary.

(2) Placing new restrictions on one (1) or more drugs on the formulary.

(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.

(c) The office shall forward the proposed change to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will:

(1) review the proposed change; and

(2) consider evidence and credible information provided to the board;

at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.

(e) **If the proposed change concerns a single source drug (as defined in section 35 of this chapter), the board may not approve the proposed change unless the board determines, after review of medical, pharmaceutical, and other relevant data, that the removal or restriction of the single source drug will not:**

(1) impede the quality of patient care in the Medicaid program; or

(2) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(f) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.

~~(f)~~ **(g)** A Medicaid managed care organization:

(1) may add a drug to the managed care organization's formulary without the approval of the office; and

(2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.